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14. ABSTRACT

The purpose of this project is to help prevent psychological disorders in high-risk individuals with early symptoms of stress, depression, substance use, and other health problems. PHIT for Duty integrates self-report and physiological sensor instruments to assess health status via brief weekly screening questionnaires in five domains (i.e., stress, anxiety, sleep quality, depression, and alcohol use). An expert system, called the intelligent virtual advisor (iVA), processes these data using evidence-based logic to determine health risk and to prescribe SHIs including mindfulness meditation, health education, and cognitive behavior change modules for reducing stress, attentional restructuring, improving sleep and reducing alcohol use. Usability studies were conducted with 31 participants using the PHIT devices, assessments, and interventions over 10 to 28-day data collections. Some participants also tested the ear pulse sensor (N=23), Zeo sleep monitor (N=27), and wrist actigraphy (N=27). Participants were debriefed on usability, technical performance, and suggestions for improvements. Usability was rated on a 1 to 5 (very hard to very easy) Likert scale, and a subset also reported on the System Usability Scale (N=9). Usability results are as follows (mean±sd): overall system (4.5±0.6), self-report instruments (4.5±0.7), ear pulse sensor (3.7±1.2), Zeo sleep monitor (4.4±0.7), Zeo sleep monitor comfort (3.7±1.1), and wrist actigraphy comfort (2.7±0.9). The average SUS was 85±12, indicating a high percentile rank of 95%. Usability evaluation of the PHIT for Duty health assessments, physiological sensors, system acceptability, and overall functionality have shown positive results and affirmation of the PHIT for Duty mobile application design.

15. SUBJECT TERMS
PTSD, post-traumatic stress disorder, mobile health, smartphone, self help, iPAD, Android

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1. INTRODUCTION

The goal of this project is to support prevention of psychological health problems and post-traumatic stress disorder (PTSD) through innovation in mobile personal health assessment and self-help intervention (SHI).

Our objective is to develop and evaluate PHIT for Duty, a field-deployable personal device to help build resilience in healthy troops and support prevention in high-risk personnel. Based on RTI's Personal Health Intervention Tool (PHIT) platform, PHIT for Duty will integrate a suite of health assessments with an intelligent virtual advisor (iVA) that recommends, tailors, and presents self-help advisories based on established rules and processes. The PHIT platform will comprise a smartphone or tablet and optional, nonintrusive physiological and behavioral sensors for health status monitoring and intervention.

PHIT for Duty is intended to be used for secondary prevention of psychological health problems in persons who have been exposed to psychological trauma and may be having some symptoms of distress, but have not been diagnosed with any psychological disease or disorder. PHIT for Duty, however, may eventually prove useful as a treatment option, and therefore should be developed according to good software development practices.

The project comprises (1) formative research to identify psychological assessments and SHIs to assist individuals in dealing with combat and operational stress and the psychological and physiological consequences of that exposure; (2) development of personal, mobile technologies for longitudinal health assessment and SHI; (3) testing, refinement, and validation of PHIT for Duty technologies through beta testing and pilot studies; (4) evaluation the efficacy of the PHIT methodology for prevention in a randomized controlled trial (RCT) with post-deployed personnel; and (5) adapting the developed system for several popular smartphone or tablet computer platforms, including both Google Android™ and Apple iOS based devices.

2. BODY

2.1. Task 1: Concept formation and development planning

The goal of this task is to establish the vision, requirements, and approach for PHIT for Duty development and evaluation through a series of interactions with scientific and clinical advisors, military leaders, prospective users, and other stakeholders. Our objective is to identify preventable psychological health problems that might be mitigated using PHIT for Duty, potential self-help interventions to incorporate in the device, operational issues regarding PHIT for Duty use post deployment, and the applicability and potential concerns for PHIT for Duty during deployment. More specifically the aim was

to identify the needs of PHIT end users and stakeholders and develop user-centric design concepts and specifications. Formative research was necessary to identify and understand the preventable psychological health problems, potential SHIs, operational requirements, and deployment concerns.

2.1.1. Focus Groups

Three focus groups were conducted during the summer of 2012 with soldiers from the Warrior Transition Battalion (WTB) at Ft. Bragg. Each session lasted approximately 90 minutes. The project team worked with a designated point of contact (POC) from the WTB to arrange the focus group sessions. The POC identified participants, explained the voluntary nature of their participation, and scheduled the focus groups. Focus groups were conducted in a private conference room housed at the WTB headquarters. A trained focus group moderator led each discussion using the RTI and WMAC IBR approved focus group moderator's guide. A note taker was also present in the room. Informed consent was obtained at the start of each focus group session. Each session was audio recorded.

There were a total of fourteen participants across three groups. All of the focus group participants were male. All participants had at least one combat deployment. The number of deployments ranged from one to six, with the average number of deployments being two. All participants had returned from deployment within the last twelve months. One participant had returned from deployment six weeks prior to the focus group session. During the focus group, the RTI team took measures to ensure that the soldiers felt emotionally and physically comfortable sharing their experiences. More specifically, participants were allowed to sit wherever they chose in the room. One participant shared that he needed to sit in "his safe space" which was across from the door and with his back to the wall. He also requested that the group not make eye contact with him as it would make him feel uncomfortable and he might "flip out." The moderator was sensitive to the vulnerability of these participants and would redirect conversations that were becoming emotionally charged.

The questions asked during each session focused on key areas that would help the research team identify psychological health problems, SHIs, operational issues, and deployment concerns. Additional topics discussed include post-deployment health problems, incentives for participation in the study, study recruitment strategies, device usage preference (tablet vs. smartphone), acceptability of proposed SHIs such as relaxation exercises, and willingness to use physiological monitoring devices.

2.1.2. Findings

Post deployment health problems. The top three post deployment health problems mentioned were depression, anxiety and sleep issues. Additional post deployment health problems discussed include stress, aggression, social withdrawal/avoidance, memory issues, substance abuse, nightmares, breathing problems, and pain. The specific types of stress mentioned include financial and relationship stress experienced after returning from deployment. Participants across all three groups discussed the stigma associated with seeking help for most post deployment health problems mentioned. It is also important to

note that soldiers reported that many post deployment health problems do not appear until a few months after return from deployment.

- "I can't stay asleep and sleep about an hour and then wake up and stay up for maybe two or three hours. This happens night after night."
- "Crowds and traffic are difficult. You are constantly on guard about people coming close to you and vehicles driving near you."
- "Nothing really happens the first three months (post deployment) when you are trying to unwind and get back into your life."

Post deployment support. Participants acknowledged the stigma associated with seeking help for most of the post deployment health problems cited above. Across all three focus groups, soldiers reported not being honest when responding to post deployment health assessments. Soldiers responded positively about the provision of post deployment support by way of an app on an electronic device. The use of this app would allow for soldiers to seek help privately without calling attention to their difficulties adjusting post deployment thus reducing the stigma and risk associated with utilizing behavioral health services. Participants recommended that the study emphasize that the names of soldiers who use the app after deployment will not be shared with the chain of command. The importance of confidentiality was repeatedly mentioned.

- "The Army offers a lot of resources (for post deployment issues) but what happens, I think, is that if a solider decides to use it he worries too much about the consequences of what people are going to think and it is like taboo and that is what it comes down to."
- "If you are labeled a soldier with PTSD then you automatically trigger thoughts of them being crazy."

Incentives. Numerous incentives were discussed during the focus groups. Soldiers reacted positively to the idea of being provided with a portable electronic device for three months. The provision and use of an electronic device would serve as an incentive for many soldiers to help encourage participation in the study if the device could be used for their personal use. Soldiers clarified that their strong preference would be for the provision of a tablet as opposed to a smartphone, as most soldiers already own a smartphone. All soldiers agreed that access to free Wi-Fi, movies, music, and games would be an incentive. The use of new and/or hard to obtain electronic devices would be an additional incentive.

- "Games like Angry Birds would be good."
- "The appeal would be the model (of electronic device) and if it were hot off the press kind of thing."

Study recruitment. A major theme that was present in all focus group discussions regarding study recruitment was the importance of stressing confidentiality and the voluntary nature of the study. Soldiers did not want their chain of command to be notified of their study participation and strongly suggested that recruitment efforts not be associated with the Army. Soldiers shared that the study team

would need to gain the trust of the soldiers. More specifically, trust that we would not share their data with their chain of command was emphasized. Once trust was established, soldiers would suggest the study to their peers which would aid in recruitment efforts. One participant thought that younger soldiers would be harder to recruit because they think they are "indestructible." Another suggested recruitment strategy was to hold "briefing" sessions off base (again stressing the separation of the study and the Army). Recruiting via Facebook or radio commercials was also suggested. Contrary to what was previously shared, one soldier recommended that we partner with Military Family Life Consultants (MFLC). MFLC are not allowed to inform the chain of command unless a soldier is threatening to hurt themself or others. Barriers to participation included the time commitment and soldiers not wanting to address post-deployment problems for fear of being identified by their chain of command. In conclusion, recruitment efforts will need to stress confidentiality and, if possible, not involve the chain of command.

- "The Military Family Life Consultants (MFLC) would be good and can't tell your chain of command and are under the radar."
- "Keep everything confidential about what is being put in that system. Keep stressing confidentiality because of the trust issue with soldiers."

Use of physiological monitoring devices. The majority of focus group members were enthusiastic and amenable to using the psychological monitoring devices (ear clip to monitor heart rate, and Zeo headband to monitor sleep). Concerns were mentioned about charging the devices. There was significant interest in monitoring sleep behaviors as many soldiers shared having sleep issues post-deployment. Soldiers were eager to receive feedback on their quality of sleep. One participant suggested the use of a sleep monitor would encourage participation and this could be focused on during recruitment. Feedback from the physiological monitoring devices may serve as an incentive for some participants.

- "I would be willing to that (wear sleep monitor). I would really like to know how I am sleeping."
- "I personally think it would be fun to see what my heart rate was doing."

General feedback. Soldiers suggested sending study reminder notifications via text message to their personal phone to ensure compliance with the daily health assessments. The length of the SHIs should be ten minutes or less per day. Soldiers would lose interest after ten minutes. We received mixed feedback on the relaxation exercises. A few participants have practiced relaxation techniques and have found them effective. Soldiers consistently shared that they are interested in receiving feedback on how their health has changed over time. One soldier feels that participants will just tell us "what we want to hear." The use of the app by family members was suggested numerous times. Soldiers feel that the family/friends could benefit from learning more about how to cope with post-deployment health issues. Soldiers recommended that the app include an easy to find resource list on phone numbers if needed.

- "The app is clean and I like it a lot".

- ”If you stress that you are building a system to help future soldiers and not say that we are analyzing them (the participant) they won’t feel like they are being judged and are more likely to help (participate).”

2.1.3. Conclusions

After reviewing these finding and discussing our observations, we arrived at the following overall conclusions:

- If possible, PHIT for Duty should be implemented three to six months post-deployment, as this is the timeframe when post-deployment health issues surface.
- The mobile electronic device of preference was the tablet.
- Study recruitment efforts will need to stress confidentiality and if possible not involve the chain of command.
- Soldiers have concerns about confidentiality.
- Soldiers are willing to use the physiological monitoring devices. Feedback provided by these devices could serve as an incentive.

2.2. Task 2: Prototype design and development

2.2.1. The Personal Health Information Tool architecture

One of our goals is to create a common mobile health platform from which many other mobile health management and data gathering applications can be readily developed, and to experiment with alternative ways of configuring the data input instruments. The PHIT system accomplishes this, in part, by integrating different forms of data inputs ranging from survey style questionnaires to diaries to external physiological and environmental sensors.

The PHIT platform is a mobile application framework that integrates multimodal data collection with an intelligent virtual advisor that analyzes real-time data to recommend, tailor, and present domain-specific activities based on established rules and scripted processes (**Exhibit 1**). PHIT facilitates building complex smartphone/ tablet applications with both self-entry and autonomous sensor-based instruments. Objective data are acquired via cognitive tests, interactive exercises, serious games, and various Bluetooth sensors. Periodic assessments of various domains are analyzed to instruct users and recommend activities tailored to the scope of the application. All acquired data are stored on the mobile device using an encrypted database, periodically uploaded to a secure server, and made available for quality review and analysis via a password-protected website.

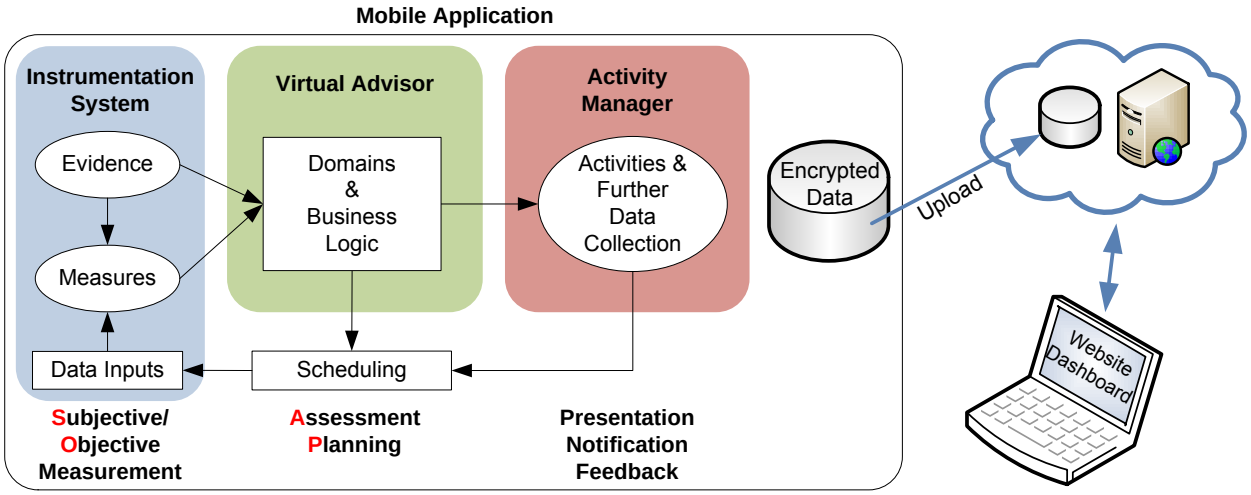

Exhibit 1. PHIT mobile application framework architecture.

The generic PHIT platform is highly extensible, flexible and secure. Developing PHIT components such as instruments, activities, and intelligent Virtual Advisor (iVA) modules is straightforward yet the XML structures provide considerable power in customizing the content. For example, sub-scores and the overall score for a user for a questionnaire (e.g., for anxiety) are immediately available to the iVA, which is able to determine how to proceed with the user. The iVA may choose to schedule a screening for a future date, to place a SHI on the user's task list, or, if necessary, contact a clinician for referral. Variations of instruments, new instruments that focus group participants suggest, and advisory content that improves the PHIT device's usability are easily accommodated.

Additionally, we have worked with clinical experts to implement a range of domains and instruments that are evidence-based, and thus justifiable. For example, the primary domains are those that clinicians feel are most important to individuals with post traumatic stress, and the iVA's underlying algorithms are written to carefully consider variation in assessments of these domains. Other data (e.g., resilience, combat exposure, and family history) are captured through additional validated and custom instruments that will be used as covariates in analyses to better explain trends found in the main domains.

A variety of widgets are available as presented in **Exhibit 2**, including:

- **Data entry**: text, number, time, date radio, checkbox, button/icon array
- **Mobile**: GPS, geolocation map, vibration accelerometer, battery
- **Sensor**: Bluetooth linked heart rate, Sony smart watch, Pebble smart watch
- **Cognitive**: reaction time, go/nogo choice reaction time
- **Output**: charts, waveform plots, formatted HTML
- **Media**: image, video, audio, slideshow, embedded browser, youTube

Exhibit 2. Examples of PHIT data collection and presentation widgets.

2.2.2. The PHIT for Duty mobile health application

The PHIT for Duty application comprises a variety of subjective and objective data collection instruments, interactive self-help activities, health information, personal feedback, and other presentation modules (**Exhibit 3**). Required user actions, like completing a brief morning sleep quality questionnaire, are managed via a task menu screen. The task list is updated each day according to logic rules managed via the intelligent virtual advisor.

A summary of the planned health assessment and preventive intervention schema is presented below (**Exhibit 4**). At baseline, personal, psychological, social, and combat history data will be collected via smartphone-based instruments. Then, on a periodic basis (e.g., bi-weekly), the user's health status is assess via brief screening questionnaires in five domains (i.e., stress, anxiety, sleep quality, depression, and alcohol use). For each domain, the screening data are analyzed by the iVA and a subsequent detailed assessment is given should the screener score meet certain criteria. Any such detailed assessment is categorized by none, mild, moderate, or likely risk of disease for that domain.

Persons with likely risk are advised to consult their primary care provider for a professional health assessment. Persons with mild or moderate risk (i.e., subclinical scores), are presented with a suite of interventional, therapeutic, and monitoring activities to support post traumatic stress reduction. These include health management information (i.e., cognitive lessons), skills acquisitions (e.g., meditation, muscle relaxation), tools (e.g., sleep hygiene checklist), and self-monitoring activities (e.g., alcohol use diary). All of these screening instruments, assessment instruments, and self-help interventional activities, as well as the iVA health management expert system, are components of the PHIT for Duty smartphone/tablet mobile application. The "to-do" list of assessments and activities to be performed by the user is updated daily and displayed on the PHIT for Duty task list screen.

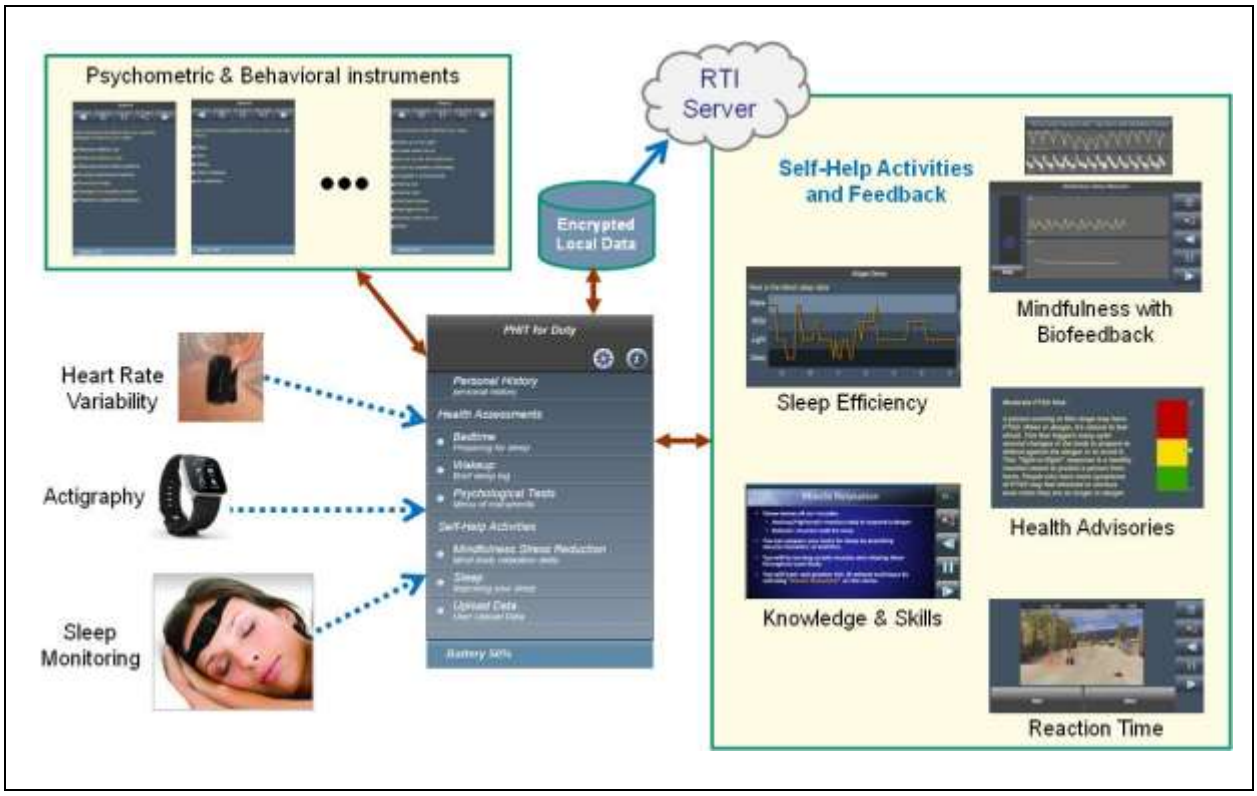

Exhibit 3. Representative data collection instruments, user task menu, self-help activities, and health information feedback modules in the PHIT for Duty application.

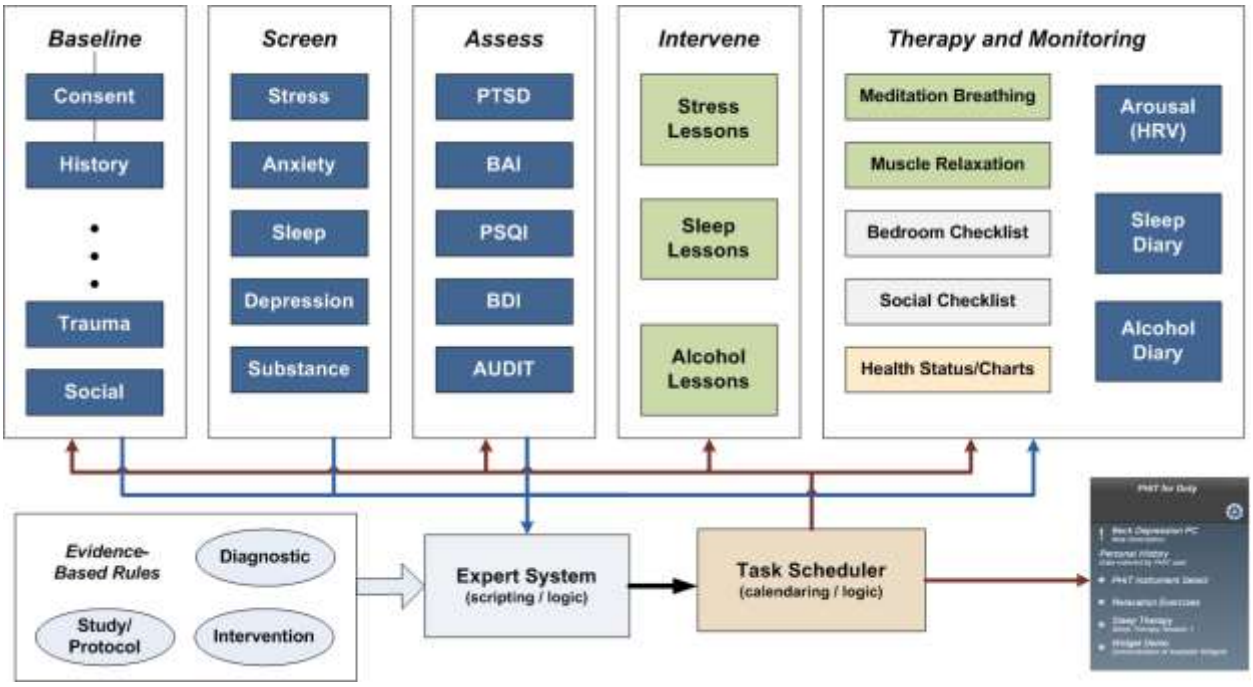

Exhibit 4. PHIT for Duty health assessment and preventive intervention schema.

2.2.3. Psychological arousal

Exhibit 5. Wireless Pulse Sensor

For objective measurement of psychological arousal, we developed a system comprising a wireless pulse sensor clipped to the earlobe (**Exhibit 5**) and software to display ear pulse, heart rate (HR), and heart rate variability The pulse sensor (Binar HeartSensor model HRS-08WE, Binar Integrated Mobile Systems, LLC, Poulsbo, WA) is a very small and unobtrusive device linked to the smartphone via a Bluetooth wireless connection, and therefore can be used to assess cardiac arousal almost anywhere and anytime. We tested the device during a range of activities at rest and during exercise, and have found the ear pulse wave to be free of artifacts and usable up to 4 hours on a battery charge.

Development of software integrating the ear lobe pulse sensor on Android mobile devices is complete. The PHIT BINAR software module receives a continuous pulse waveform sampled at 300 Hz, uses several digital filters to clean the waveform, and provides these data to the PHIT heart rate (HR) analysis module as a real time background process. At a specified interval (e.g., every 5 seconds), the HR analyzer examine the prior 60 seconds of pulse information and determines the average HR, the average interbeat interval (IBI), and measures of HR variability (e.g., RSA). The raw and clean HR waveforms and derived HR and HRV measurements are stored in the PHIT database and plotted on the device (**Exhibit 3**).

2.2.4. Psychometric assessment and scheduling

Based on the design inputs set by our internal science team, a suite of psychological, behavioral, social, and other health assessments has been developed (**Exhibit 6**). Each assessment instrument (e.g., Pittsburgh Sleep Quality Index) was scripted using an XML-based language as specified in the PHIT architectural documentation. The science team has also scripted the iVA logic, which will direct the scheduling of instruments based on a set of logic rules.

These health assessments comprise a range of health domains, including trauma exposure, PTSD symptoms, anxiety, depression, sleep quality, and substance use. Some measures will be taken only at baseline, such as the Combat Exposure Scale. Others will be taken periodically (e.g., weekly) as screeners, and if instrument-specific thresholds are exceeded, a more detailed assessment will be made via another instrument. The status of these periodic health assessments will be used to recommend stratified self-help interventional activities to be carried out by the user on the smartphone. The decisions about which screeners, instruments, and SHI to present will be made by the iVA.

Exhibit 6. Self-assessment Instruments Implemented for the PHIT for Duty Study

Baseline instruments

Personal Data	User Demographics and History	n/a
Combat exposure	Combat Exposure Scale (CES)	Keane et al., 1989
Head injury	Concussion Checklist (CCL)	McCrory et al., 2004
Coping	Brief Coping Scale (BCOPE)	Carver, 1997
Resilience	Connor-Davidson Resilience Scale (CDRS)	Connor et al., 2003
Emotional Regulation	Difficulties in Emotion Regulation Scale DERS)	Gratz and Roemer, 2004
Distress	Impact of Event Scale (IES)	Horowitz et al., 1979

Monitoring instruments

PTSD	Short Screening for PTSD (PTSD7)	Breslau et al., 1999
Sleep	Insomnia Severity Index, with nightmares (ININ)	Buysse et al., 1989
Alcohol	Alcohol Use Disorder Identification Test - Consumption (AUDIT-C)	Babor et al., 2001
Anxiety	General Anxiety Disorder (GAD7)	Spitzer et al., 2006
Depression	Patient Health Questionnaire (PHQ)	Kroenke, K., et al., 2009

Full-scale assessment instruments

PTSD	PTSD Checklist-Military (PCLM)	Weathers et al., 1993
Sleep	Pittsburgh Sleep Quality Index (PSQI)	Buysse et al., 1989
Alcohol	Alcohol Use Disorder Identification Test (AUDIT)	Babor et al., 2001
Anxiety	Beck Anxiety Inventory (BAI)	Beck et al., 1988
Depression	Patient Health Questionnaire (PHQ)	Kroenke, K., et al., 2009

Secondary measures

Stress	Perceived Stress Scale-4 (PSS4)	Cohen et al., 1983
Stress	Perceived Stress Scale-10 (PSS10)	Cohen et al., 1983
TBI	Rivermead Post Concussion Symptoms Questionnaire (RPQ)	King et al., 1995
TBI	The Brief Traumatic Brain Injury Screen (TBI3)	Schwab et al., 2006
Social	Multidimensional Scale of Perceived Social Support	Zimet et al., 1988
Sleep	Pittsburg Sleep Quality Index Addendum (PSQIA)	Germain et al., 2005
Reactivity	Simple Reaction Time	Lathan, et al., 2013
Reactivity	Go/NoGo Reaction Time	Lathan, et al., 2013

2.2.5. Sleep quality

Since sleep problems are frequently associated with Hyperarousal and PTSD (Gellis et al., 2010), we proposed to develop some measurement technology for objective assessment of sleep quality, rather than a mere questionnaire (e.g., PSQI), that could be used in near real time with smartphones or other portable devices. Actigraphy, which employs motion sensors attached to the wrist, is an obvious candidate; however the commercially-available systems do not interface with smartphones. Furthermore, actigraphy has been found to be better in assessing sleep/wake cycles rather than sleep quality (Pollak et al., 2001). Consequently we were looking at alternatives.

Exhibit 7. Zeo Headband

A relatively new device that we have begun to evaluate is the Zeo Sleep Manager (Zeo Inc., Newton, MA). This validated device (Shambroom et al., 2012) uses an unobtrusive headband (**Exhibit 7**) to sense sleep patterns and send the data wirelessly to a mobile device, on which the patterns of REM, light and deep sleep and wakefulness are charted. Software integrating the Zeo sleep monitor software on Android mobile devices is complete. The Zeo sleep manager mobile sleep monitoring sensor device uses an unobtrusive headband to sense sleep patterns and send the data wirelessly to a mobile device, on which the patterns of REM, light and deep sleep and wakefulness are charted. Zeo provided us with a software-development kit so that we could transfer the acquired sleep data each morning from the Zeo software to the PHIT for Duty database. After receiving the Zeo data, a chart of sleep efficiency is produced and made available for user feedback (**Exhibit 3**).

As another objective measure of sleep quality, we intended to use the W3Tilt Bluetooth 3 axis accelerometer as a measure of body movement based on software previously developed under a concept award. However, the device is no longer on the market. Recently Sony released their SmartWatch which includes a 3-axis accelerometer in a wrist-worn package and wireless Bluetooth communication to Android devices. We therefore began developing software to integrate the Sony SmartWatch accelerometer sensor with the PHIT platform. We have found that we can acquire reliable 3-axis body motion data at 5 Hz using this device and will integrate it into the PHIT sensor library.

2.2.6. Self-help interventions

Development of the health intervention and self-help activity presentation modules continued with new content being created for stress management, mindfulness stress relaxation, alcohol use reduction, and sleep improvement interventions. The self-help intervention materials generally fall into two categories: learning materials presented as slide shows or narrated videos and interactive activities of various types depending upon the domain (**Exhibit 8**).. The intervention modules are listed below.

Exhibit 8. Self-help interventions including learning materials and interactive activities.

Stress Management

- Learning materials (each is a 5-10 minute presentation)
  - Arousal control
  - Attention absorption
  - Combat and Operational Stress
- Self-help activities/monitoring
  - Attention absorption – narrated 15 minute meditation exercises
  - Mindfulness training, below

Mindfulness Stress Relaxation

- Learning materials (each is a 5-10 minute slide presentation)
  - Mindfulness, an introduction
  - Mindfulness course
  - Informal Practice
  - Attitudes for Mindfulness
  - Autopilot
  - Barriers to Practice
  - Breathing meditation
  - Three Minute Breathing Space
  - Daily Mindfulness
  - Thoughts are not Facts
  - Allowing and Letting Be
  - Busy, Background, Being Mind
  - Body Scan Tips
  - Staying Present
- Self-help activities
  - Mindfulness breathing – 10 minute audio-guided meditation
  - Breathing space – 3 minute audio-guided meditation
  - Body scan meditation – 5 and 15 minute audio-guided meditations
  - Sitting meditation – 10, 15, 20, and 30 minute audio-guided meditations
  - Quiet sitting meditation – 30 minute unguided meditation
  - Formal walking meditation – 10 minute audio-guided meditation
  - Informal walking meditation – 6 minute audio-guided meditation
  - Lovingkindness meditation – 15 minute audio-guided meditation

Sleep Improvement

- Learning materials (each is a 5-10 minute presentation)
    - Improving you sleep
    - Preparing for sleep
    - Personal and environmental factors
    - Reclaiming your bedroom
    - Sleep smarter skills
    - Dealing with nightmares
    - Sleeping well
- Self-help activities/monitoring
    - Daily wakeup sleep log
    - Daily bedtime sleep preparation log

Alcohol Use Reduction

- Learning materials (each is a 5-10 minute slide presentation)
    - Stress and alcohol
    - Facts about drinking
    - Drink smarter
    - Risks of alcohol use
    - Reducing alcohol use
- Self-help activities/monitoring
    - Personal behavior assessment
    - Goal setting for alcohol reduction
    - Weekly goal tracking log, with feedback
    - Readiness to change (RTC) questionnaire for alcohol use
    - Single question RTC reassessment Likert test
    - Blood alcohol level simulation - interactive/ serious game

Because of the high risk of binge drinking as a coping behavior for post-traumatic stress, particularly in young adults, we decided to implement a cognitive behavior therapy (CBT) intervention, with motivational interviewing (MI) constructs, to help curb binge drinking for persons at risk. To support the intervention, we developed a schema for implementing a self-directed interactive CBT/MI intervention and a suite of educational modules on various aspects of alcohol use and risk, and questionnaires for assessing readiness to change. The intervention schema is presented in **Exhibit 9**.

Participants who complete the AUDIT assessment will receive a brief statement about their alcohol risk and a slide presentation on Stress and Alcohol. Persons with moderate and high risks of alcohol use will then receive a readiness to change (RTC) questionnaire. Persons who are contemplating change, or a pre-contemplative, will receive information on risks of alcohol use, and then be reassessed for their readiness to change their drinking behavior. Persons who are ready to change will receive the reducing alcohol use education module (Alcohol-Change), information on setting goals for reducing alcohol use, and assistance in managing their behavior change via the PHIT for Duty app.

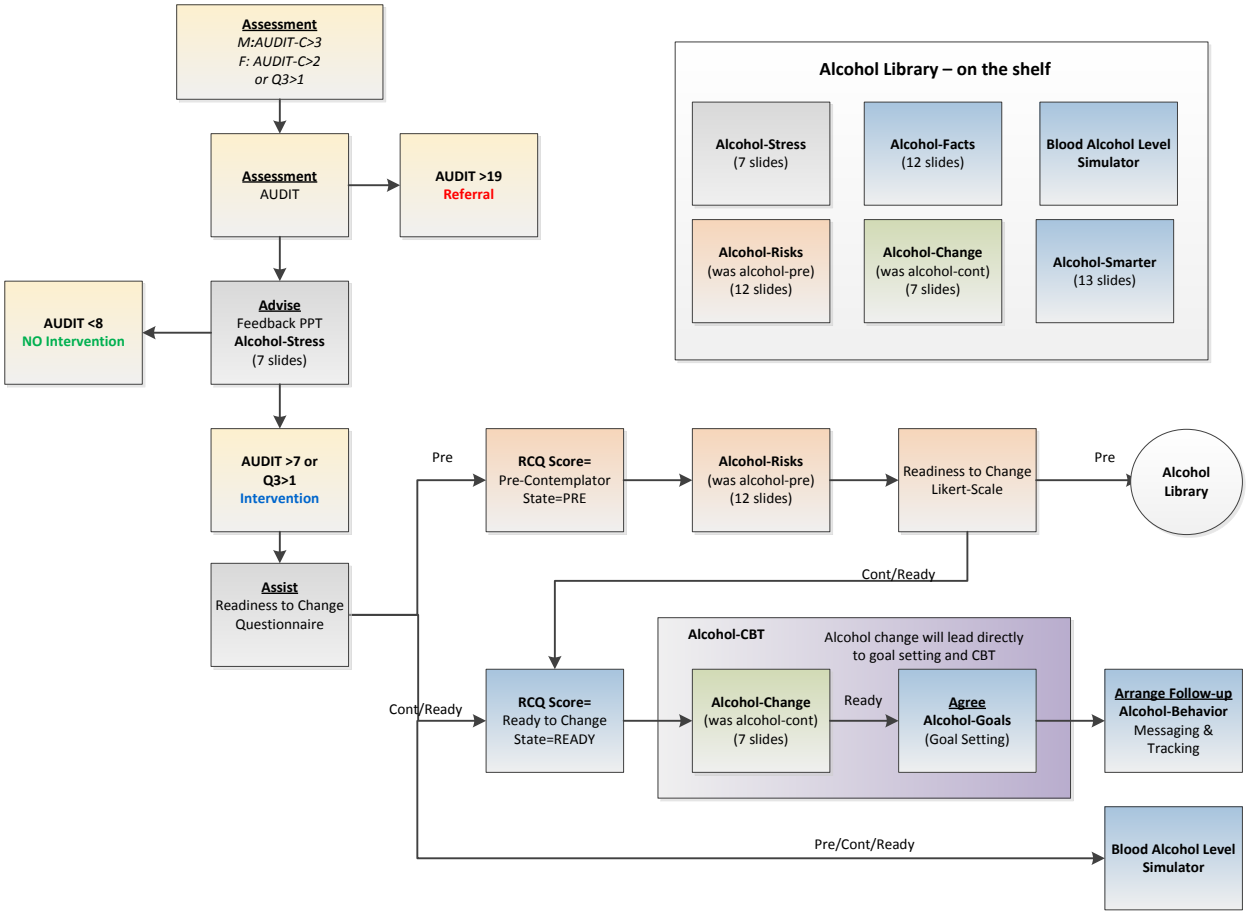

Exhibit 9. Cognitive behavior intervention for alcohol use.

All users will be able to freely view all of the alcohol education modules via an "Alcohol Library", including the additional modules on facts about drinking (Alcohol Facts) and drink smarter skills (Alcohol-Smarter). Users will also have access to the blood alcohol level (BAL) simulator. The BAL simulator allows the user to enter information about a series of drinks to be consumed over a period of time (i.e., 4 hours), and to plot the time course of BAL during and after consumption. They can then interact with the plot and observe how changing the drinking pattern can affect their estimated BAL and time to fall below the legal driving limit. They will also be able to replace any drink in the scenario with an alternative (i.e., water or cola), and then to repot this new scenario against the previous one and compare outcomes. The BAL simulator provides an interactive, game-like learning experience on the relationship between alcohol consumption and the time-course of alcohol intoxication.

2.3. Task 3: Beta testing in civilians

2.3.1. Developmental usability evaluations

Usability was evaluated in a series of at-home studies ranging from 7-14 days in 31 participants conducted throughout 2013 to evaluate functionality and performance, gain user feedback, and yield usability measures of system features (**Exhibit 10**). These studies were designed to engage participants in various aspects of the PHIT for Duty devices, software modules, assessment instruments, and intervention activities. Testing was performed in waves of five participants, allowing time between waves for revising software and procedures based on user feedback.

Prior to testing, informed consent was acquired, training was given, and a user manual was provided. Participants took their PHIT devices home and performed a series of scheduled activities over a designated time frame. Self-report assessments and diaries were tested using a mix of sham and actual data including daily bedtime and wakeup sleep diary entries, mindfulness-based stress reduction training with heart rate variability biofeedback, simple reaction time testing, and additional health assessments and intervention activities. Some participants also tested the ear pulse sensor (N=23), Zeo sleep monitor (N=27), and wrist actigraphy (N=27). Participants were debriefed on system usability, technical performance, and suggestions for improvements via a common debriefing questionnaire. Summary results for the primary usability components are as follows:

Exhibit 10. Integrated usability test results.

System and Device Usability - Range of 1 to 5 (very hard to very easy)

PHIT Subsystem	*Mean ± SD*	*N*
Overall system	4.5 ± 0.6	31
Self-report instruments	4.5 ± 0.7	31
Ear pulse sensor	3.7 ± 1.2	23
Zeo sleep monitor	4.4 ± 0.7	27

Sleep Monitor Comfort - Range of 1 to 5 (very uncomfortable to very comfortable)

PHIT Subsystem	*Mean ± SD*	*N*
Zeo sleep monitor	3.7 ± 1.1	27
Wrist actigraphy	2.7 ± 0.9	27

2.3.2. Civilian testing simulating planned Fort Bragg pilot test conditions

In the final beta field test protocol, five civilian participants were asked to act as simulated post-deployed military personal with different and varying health conditions, and to enter sham health data according to specified (simulated) levels of PTSD, sleep problems, anxiety, depression, and alcohol use. Each participant received instruction as to their initial simulated health status for each of five health domains as well as weekly changes in health status over the 28-day beta test. In this manner we were able to exercise most aspects of the PHIT for Duty assessment tools and self-help intervention activities.

A subset of the field test data is presented below ((**Exhibit 11**). These data report on the initial baseline and subsequent weekly assessments entered by the field participants across five health domains: post-traumatic stress (PCL), sleep quality (PSQI), alcohol use (AUDIT), depression (PHQ8), and anxiety (GAD7). Highlighted measures indicate when threshold criteria were met, and in turn the appropriate health intervention activities would be provided to the user. While these are only sham data, they do illustrate how the PHIT for Duty software is used to acquire weekly health data, upload results to a central data store, and prescribe health interventional activities according to individual need.

Exhibit 11. Weekly PHIT for Duty health assessments from civilian beta test participants.

CaseID	Char	Week	PTSD	PCL>30	Sleep	PSQI>8	Alcohol	AUDIT>8	Depression	PHQ8	Anxiety	GAD7
3010	1	0	Moderate	**62**	Major	**12**	Heavy	**9**	Very	20	Very	8
	1	1	Moderate	**57**	Major		Heavy		Very	13	Very	10
	1	2	Moderate	**46**	Major		Heavy		Very	12	Very	10
	1	3	None	22	None		None		None	0	None	0
	1	4	None	17	None	9	None	0	None	0	None	0
3011	2	0	None	24	None	4	None		None		None	
	2	1	None	19	None		None		None	0	None	0
	2	2	Moderate	20	None		Moderate		None	0	Minor	0
	2	3	Moderate	20	Major		Heavy		None	0	Very	0
	2	4	Moderate	17	Major		Heavy	5	Slight	0	Very	0
3012	3	0	High	**63**	Minor		None		None	0	None	5
	3	1	High	**54**	Minor		None		None	0	Minor	5
	3	2	High	**57**	Minor		None		None	0	Minor	5
	3	3	None	17	Minor		Moderate		Slight	6	Minor	6
	3	4	None	17	Major		Moderate		Slight	2	Minor	4
3013	4	0	High	**65**	None	6	Moderate		Slight	11	None	3
	4	1	High	**59**	None		Moderate		Slight	10	None	3
	4	2	High	**44**	None		Moderate		Slight	8	None	4
	4	3	None	**35**	None		Moderate		Slight	7	None	5
	4	4	None	27	Major	7	Heavy		Very	16	Minor	9
3014	1	0	Moderate	**37**	Major	**13**	Heavy	**16**	Very	15	Very	12
	1	1	Moderate	**48**	Major	**14**	Heavy	**31**	Very	24	Very	14
	1	2	Moderate	**48**	Major	7	Heavy	0	Very	17	Very	13
	1	3	None	22	None		None		None	0	None	0
	1	4	None		None		None		None		None	

Unfortunately, there are missing health scores in this table. In some cases, the participant simply skipped his or her data entry for that week. In other cases, the participant started, but did not complete, the health assessment instrument, and so the domain score could not be computed. We know this because a number of incomplete instruments were uploaded to the central data store. Identifying such problems in these field tests is useful in they can be addressed by software modifications and by providing additional reminders to the participant. For example, an audible notification like a cell phone text message receipt can be provided to help ensure participant compliance. Any such revisions in the data collection instruments will be made and thoroughly tested prior to beginning the pilot study at Fort Bragg.

2.3.3. Overall system usability evaluation

The System Usability Scale (SUS) was used to quantify usability of the PHIT for Duty system in last four participants of the14-day day field test and the five participants of the 28-day simulated pilot test. The average SUS score reported by these nine participants was 85±12 (mean±sd). The percentile rank for this average score is 95%, meaning that the usability of the near-final PHIT for Duty system exceeds 95% of all products tested using the System Usability Scale. For more information on the SUS, view:

http://www.usability.gov/how-to-and-tools/methods/system-usability-scale.html

2.4. Task 4: Pilot study in service members

Attaining approval for the pilot study protocol at Fort Bragg has been a challenge. In November 2013, the WAMC Scientific Review Committee reviewed the protocol and recommended that it proceed to the IRB for review. After several reviews and submission of addenda, the protocol was provisionally approved in March 2014, pending four minor modifications. Another IRB review will be conducted in April which we expect to grant full approval. The Pilot Study should start in June 2014.

2.5. Randomized controlled trial in post-deployed personnel

No work to date on this task.

2.6. Task 6: Migration to other smartphones and tablets

As mobile devices become more prevalent, so does the range of possibilities for medical applications to gather data using these devices. Since the user community employs a variety of technologies, and development tools vary across platforms, engineers generally select a single platform for development. This approach reduces the number of devices the application can run on, reduces new features, and imposes additional cost while the team re-implements the application for different smartphone and tablet devices.

To avoid these issues, we examined several cross-platform development tools to determine their efficacy and applicability for PHIT development. The result was our selection of Adobe Flash Builder for software development and the Adobe Interactive Runtime (AIR) for execution on multiple mobile platforms (**Exhibit 12**). Applications developed for Adobe AIR will not only execute on devices using the

Google Android and the Apple iOS operating systems, but also on Microsoft Windows and Apple desktop computers. Of course not all of the features may be supported on all devices, such as GPS location identification, as such resources are not universally available. However, the software is designed to tailor itself to those resources that are available, and for which the user has govern permission.

Using Adobe Flash Builder, software is developed in Adobe ActionScript, an advanced object-oriented language that is very similar to Java and JavaScript. Packaging for Android or iOS is as easy as selecting the particular export platform when building the project. For Android, the package requires the Adobe AIR runtime to be installed on the mobile device. For iOS, a native iOS binary is generated which includes all necessary runtime support.

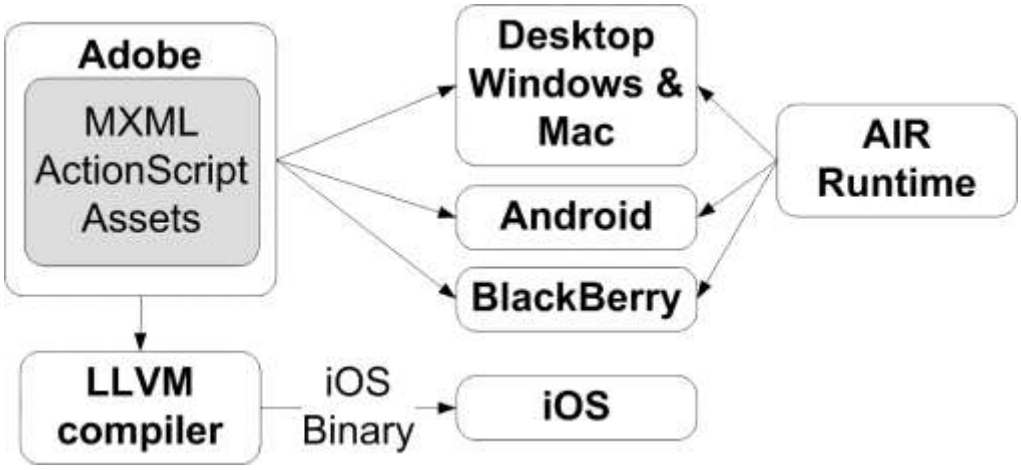

Exhibit 2. Cross-platform development methodology using the Adobe AIR runtime.

3. KEY RESEARCH ACCOMPLISHMENTS

To date the main research accomplishments have been development of the PHIT mHealth platform, development of the PHIT for Duty mHealth application, and demonstration of a high level of usability in an age-appropriate civilian population.

The PHIT mHealth platform is being built is highly extensible, flexible, and secure. The platform facilitates designing instruments, user displays, task scheduling and data storage, so researchers can create a mobile application in much shorter time than development from scratch. Developing PHIT for Duty components such as instruments, activities, and iVA modules is straightforward yet the XML structures provide considerable power in customizing the content. For example, subscores and the overall score for a user for a questionnaire (e.g., for anxiety) is immediately available to the iVA, which is able to determine how to proceed with the user. The iVA may choose to schedule a screening for a future date, to place a SHI on the user's task list, or, if necessary, contact a clinician for referral. Variations of instruments, new

instruments that focus group participants suggest are important, and advisory content that improves PHIT for Duty usability are all able to be easily accommodated. Researchers can focus on the protocol, instruments, and interventions without having to worry about how the application is constructed, thereby implementing and evaluating mobile health interventions in less time and lower effort.

PHIT for Duty, a mobile health application for reducing the impact of stress exposures in military personnel, provides psychological health assessment and tailored health interventions on a smartphone or tablet platform. We have worked with clinical experts to implement the PHIT for Duty application to include a range of domains and instruments that are evidence-based, and thus justifiable. For example, the primary domains are those that clinicians feel are most important to the target population for PHIT, and the iVA's underlying algorithms are written to carefully consider variation in assessments of these domains. Other data (e.g., resilience, combat exposure, and family history) are captured through additional validated and custom instruments that will be used as covariates in analyses to better explain trends found in the main domains. With mobile technology, PHIT for Duty provides privacy which may help reduce stigma and encourage user adherence to personal assessment and interventions. Initial evaluations of PHIT instrument interactions, physiological sensors, system functionality, system acceptability, and overall usability have shown positive results and affirmation of the PHIT mobile application framework design. We look forward to evaluating the effectiveness of the PHIT for Duty mHealth app for mitigating post-traumatic stress in post-deployed military personnel at Fort Bragg. These evaluations will commence with a Pilot Study in the summer of 2014, and will be followed by a Randomized Controlled Trial to begin later in the year.

4. REPORTABLE OUTCOMES

4.1. Manuscripts, abstracts, presentations

During the last project year, the following publications and presentations were made based on projects using either the PHIT framework or the PHIT for Duty mobile application:

Kizakevich, P. N., Eckhoff, R. P., Bakalov, V. D., Zhang, Y., Bryant, S. P., Lyden, J. T., Weger, S. A., Weeks, A. L., & Brown, J. M. (2013, October). *PHIT for Duty, a Mobile Health Assessment and Intervention Application for Post-Traumatic Stress and Psychological Disorders*. Poster presented at Inaugural Symposium on Using New Technologies to Enhance Healthy Behaviors, Chapel Hill, NC.

Kizakevich, P. N. (Invited Speaker). (2013, November). *Implementing PHIT, a mHealth Toolkit for Posttraumatic Stress and Health Intervention Research*. Presented at DoD/VA mHealth Summit, Arlington, VA.

Hourani, L. L., Kizakevich, P. N., Tueller, S. J., Weimer, B. J., Lewis, G. F., & Bryant, S. P. (Invited Speaker). (2013, August). *Combat Stress Casualty Reduction: Development and Testing of a Predeployment Stress Inoculation Training Program*. Presented at Military Health Services Research Symposium, Ft. Lauderdale, FL. Weger, S. A., Kizakevich, P., Eckhoff, R. P., Zhang, Y., Lyden, J. T., Bakalov, V. D., & Bryant, S. P. (2013, May). *PHIT for Duty: Exploring a mobile data collection framework*. Presented at AAPOR Annual Conference, Boston, MA.

Bagwell, J. E., Furberg, R. D., Kizakevich, P. N., Eckhoff, R. P., Zhang, Y., Bakalov, V. D., Simoni, D. A., Hobbs, C. L., & LaBresh, K. A. (2013, April). *A mobile clinical decision support tool for implementing the NHLBI Expert Panel Integrated Guidelines for Cardiovascular Health and Risk Reduction in Children and Adolescents*. Poster presented at mHealth@Duke 2013, Durham, NC.

During the previous project years, the following publications and presentations were made based on projects using either the PHIT framework or the PHIT for Duty mobile application:

Kizakevich, P. N., Eckhoff, R. P., Lyden. J., Hubal, R, and Brown, J.. (2013, February). *PHIT for Duty™, a Mobile Health Assessment and Intervention Application for Post Traumatic Stress and Psychological Disorders*. Poster presented at Digital Health Communication Extravaganza, February 21, 2013, Orlando, FL.

Kizakevich, P. N., Hubal, R. C., Brown, J. M., Lyden, J. T., Spira, J. L., Eckhoff, R. P., Zhang, Y., Bryant, S. P., & Munoz, G. (2012). PHIT for Duty, a Mobile Approach for Psychological Health Intervention . *Studies in Health Technology and Informatics*, *181*, 268–272. doi:10.3233/978-1-61499-121-2-268

Bagwell, J. E., Furberg, R. D., Kizakevich, P. N., Eckhoff, R. P., Zhang, Y., Bakalov, V. D., Simoni, D. A., Hobbs, C. L., & LaBresh, K. A. (2013, April). *A mobile clinical decision support tool for implementing the NHLBI Expert Panel Integrated Guidelines for Cardiovascular Health and Risk Reduction in Children and Adolescents*. Poster presented at mHealth@Duke 2013, Durham, NC.

Zhang, Y., Roe, D. J., Keating, M. D., Kizakevich, P. N., Eckhoff, R. P., Bryant, S. P., Munoz, G., & Hubal, R. C. (2012, May). *SurveyPulse - A Cross-Platform Mobile Survey App Created with Adobe Flex*. Presented at IFDTC, Orlando, FL.

Kizakevich, P.N. (2012, January). *Mobile technologies for health monitoring and intervention*. Invited presentation, Raleigh Engineers Club, Raleigh, NC.

Eckhoff, R.P., Kizakevich, P.N., Zhang, Y., & Hubal, R.C. (2012, February). *Personal Health Intervention Tool: A mobile framework using Adobe Flash Builder*. Poster presented at the Digital Health Communication Extravaganza, Orlando, FL.

Hubal, R. (2012, April). *The imperative for social competency prediction*. Talk presented at the Social Computing, Behavioral Modeling and Prediction Conference, College Park, MD.

4.2. Licenses applied for and/or issued

- No patents or disclosures have been filed.
- RTI plans to copyright the PHIT platform and PHIT for Duty source code and application.
- The PHIT platform may be recognized as a medical device; currently an investigational device exemption has been granted by RTI's IRB.

4.3. Degrees obtained that are supported by this award

None

4.4. Development of cell lines, tissue or serum repositories

Not applicable

4.5. Infomatics such as databases and animal models

None

4.6. Funding applied for based on work supported by this award

The PHIT mobile technology framework has been instrumental in the expansion of mobile application and intervention research across a variety of health domains. The following research projects have made use of either the PHIT framework or the PHIT for Duty application as a key component:

- **PHIT for Duty- psychological and physiological data validation studies**
  Office of Naval Research, P. Kizakevich, PI
- **Predeployment Stress Inoculation Training Program**
  Office of Naval Research, Dr., L. Hourani, PI
- **Predeployment Stress Inoculation Training Program**
  Department of Defense PTSD research program, MOMRP, Dr. L. Hourani, PI
- **A mobile clinical decision support tool for implementing the NHLBI Integrated Guidelines for Cardiovascular Health and Risk Reduction in Children and Adolescent**
  National Heart, Lung, and Blood Institute, Dr. Ken LaBresh, PI.
- **ActiSleep sleep diary for data collection in an adolescent sleep and marijuana study**
  National Institute on Drug Abuse, Dr. D. Fishbein, PI

- **PHIT for Flight mHealth app for substance abuse reduction in flight attendants**
  Substance and Mental Health Services Administration, P. Kizakevich, Lead Developer

4.7. Employment or research opportunities applied for and/or received based on experience/training supported by this award

During the last project year, the research opportunities listed below have been applied for based on projects using either the PHIT mobile technology framework or the PHIT for Duty mobile application.

- **Preventing Addiction during Military Deployment**
  National Institute on Drug Abuse, Dr. R.Tartar, University of Pittsburgh, PI

- **Developing Effective HIV Prevention Approaches with Young African American Families,** National Institute on Drug Abuse, Dr. W. Wechsberg, PI

- **An Online Tool for Alcohol Prevention in Veterans**
  Old Dominion University, Dr. L.Stambaugh, PI

- **Adaption of Mindfulness Training to Treat Chronic Pain in the Military**
  National Center for Complementary and Alternative Medicine, Dr. S. Miller, PI

- **Applicability of Mindfulness Breathing Techniques for Pain Management in US Military**, National Center for Complementary and Alternative Medicine, Dr. L. Hourani, PI

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